

### **REMARKS/ARGUMENTS**

Reexamination and reconsideration of this Application, withdrawal of the rejections, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above claim amendments and remarks that follow.

Claims 43, 44, and 45 have been amended to recite that the insulin comprises insulin alone or in combination with an insulin analog selected from the group consisting of insulin lispro analogs, humalog insulin, super insulin analogs, and combinations thereof. Support for these amendments can be found specifically in paragraph [0068] of the originally filed specification. Claim 43 has also been amended to recite that none of the insulin is encapsulated by the microparticles. Claim 44 has also been amended to recite that the microparticles do not act as shells with the insulin inside the shells, and none of the insulin is encapsulated by the microparticles. Claim 45 has also been amended to recite that the microparticles do not act as shells with the insulin inside the shells, but rather the insulin is only in the microparticles by being located in pores of the microparticles. Support for these amendments can be found specifically in paragraph [0073] of the originally filed specification. Claims 26 and 42 have been canceled. Claims 27-37, 41, and 43-45 are pending.

#### Rejections under 35 U.S.C. §112

Claims 26-37 and 41-45 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Although Applicant does not agree with the rejection, claims reciting insulin have been amended to recite insulin or specific analogs thereof. Applicant submits that the amendment clarifies that the insulin in the recited compositions is insulin or the specifically recited analogs. In light of this amendment, Applicant respectfully requests reconsideration and withdrawal of the rejection.

#### Rejection under 35 U.S.C. §102

Claims 26-29, 32, 35, 37, and 41-45 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Schröder (Methods in Enzymology, 1985). Similarly, claims 26-29, 32, 35, 37, and 41-45 stand rejected under 35 U.S.C. §102(b) as allegedly being

anticipated by Schröder (U.S. Patent No. 4,713,249). Applicant respectfully traverses these rejections.

Independent claims 43, 44, and 45 have been amended, as described above. Pending claims 27-29, 32, 35, 37, and 41 all ultimately depend from claim 44. Thus, the rejected claims all recite subject matter that is not disclosed by either Schröder document. Schröder only teaches encapsulating active agents (i.e., using microparticles as shells with the insulin inside the shells). The present claims exclude such encapsulated compositions.

The Examiner argues that “some” amount of the active agent encapsulated by the microparticles in Schröder “could” at some time be released from the microparticles. Schröder, however, still teaches that some amount of its active agent is encapsulated, and the present claims exclude such possibility. Moreover, Schröder does not disclose microparticles with insulin in pores of the microparticles, particularly where the insulin is only in the microparticles by being in the pores.

In light of the above, Applicant submits Schröder fails to disclose each and every element of the rejected claims. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the present rejections.

#### Rejections under 35 U.S.C. §103

Claims 33 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) in view of Moriyama (Journal of Controlled Release, 1996). Claims 31 and 36 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) in view of Ecanow (U.S. Patent No. 4,963,526). Claims 30 and 34 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Schröder (Methods in Enzymology) in view of Clark et al. (U.S. Patent No. 5,783,556). Applicant respectfully traverses these rejections.

Schröder (Methods in Enzymology) fails to disclose or teach each and every aspect of claim 44. Presently rejected claims 30, 31, 33, 34, and 36 all depend from claim 44. Applicant submits that the cited secondary references fail to cure the deficiencies of Schröder (Methods in Enzymology). Accordingly, Applicant submits the rejected claims are not

obvious over the cited combinations, and Applicant respectfully requests reconsideration and withdrawal of the present rejections.

Applicant respectfully submits that all claims, as now submitted, are in condition for immediate allowance. Accordingly, a Notice of Allowance is respectfully requested in due course. If any minor formalities need to be addressed, the Examiner is directed to contact the undersigned attorney by telephone to facilitate prosecution of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

/ryan w. cagle/

Ryan W. Cagle  
Registration No. 47,468

**Customer No. 00826**  
**ALSTON & BIRD LLP**  
Bank of America Plaza  
101 South Tryon Street, Suite 4000  
Charlotte, NC 28280-4000  
Tel Raleigh Office (919) 862-2200  
Fax Raleigh Office (919) 862-2260

*ELECTRONICALLY FILED USING THE EFS-WEB ELECTRONIC FILING SYSTEM OF THE UNITED STATES PATENT AND TRADEMARK OFFICE ON July 23, 2008.*